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09/380,826	11/22/1999	RODERICK J. CHAPPEL	DAVIE79.001A	3117

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/380,826

Applicant(s)

CHAPPEL

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20,75 and 124-126 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20,75 and 124-126 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed January 10, 2003 has been entered. Claims 1,17,19, 75, 124 and 125 have been amended. Claims 1-20, 75 and 124-126 are under consideration in the office action.

Response to Arguments

2. Applicant's arguments filed January 10, 2003, have been fully considered however they are not found persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The written description rejection of claims 1-20, 75 and 124-126 under 35 U.S.C. 112, first paragraph is maintained.

In particular, claim 1 is drawn to an isolated pathogenic *Leptospira* bacterium that a) belongs to serovar hurstbridge and is cross-reactive in a cross-agglutination assay with deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684; b) belong to sero group Hurstbridge and cross-agglutinates with shared group antigens of

deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684 and does not cross-agglutinate with members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and the bacterium comprises genomic DNA which is at least 40% homologous to the DNA derived from deposited *Leptospira fainei* strain WKID AGAL Accession NO. N95/69684.

The specification does not provide evidence of a *Leptospira* bacterium that a) is cross reactive in a cross-agglutination assay with deposited strain; b) cross-agglutinates with shared group antigens of the deposited strain and does not cross-agglutinate with members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and the comprises genomic DNA which is at least 40% homologous to the DNA derived from deposited *Leptospira fainei* strain WKID AGAL Accession NO. N95/69684.

Applicants have failed to show a bacterium with the recited features.

There is evidence that other bacterial species have not yet been identified and/or classified into the stated serovars. In view of the lack of evidence, it is apparent that Applicants were not in possession of additional bacterial strains, at the time of filing the instant application such as an isolated pathogenic *Leptospira* bacterium that meets the claimed definition.

The specification at pages 4 and 5 define the term serovar and serogroups but do not teach the identity of bacterial strains that cross-react in cross-agglutination assays to the deposited strain. Page 4 lines 11-17 state that members of the serogroup Hurstbridge refers to a serological group of *Leptospira* whose members cross-agglutinate with shared group antigens of *L. fainei* deposited strain; however the

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specification does not state the identity or structural characteristics of a cross-reactive strain that has the claimed growth characteristics or the claimed ability to infect.

Adequate support for the isolated bacterium is provided only for the structural identity of the bacterium, not characteristics that an unidentified bacterium will have. Examples 4 and 5 describe agglutination assays and examples 8-11 teach how to determine whether a bacterium is related to the deposited strain. However, none of the examples teach the identity of the isolated bacterium to which the claims are drawn.

Applicants assert that the specification not only discloses the deposit number of an exemplified isolated bacterium but also the sequence as described by SEQ ID NO:1. However this assertion is incorrect. The claims are drawn to an isolated bacterium that is either cross-reactive to the deposited strain, cross-agglutinates with share antigens of the deposited strain or has at least 40% homologous DNA with the deposited strain. Therefore the claims are not drawn to the deposited strain but to another bacterium which shares the defined characteristics. Therefore, even though the characteristics are defined, applicant is attempting to claim a bacterium of which they did not have possession.

It is noted that sequence identity/similarity is not equivalent to sequence homology. The term homology refers to structural similarities among organisms DNA. Thus, different sequences can be homologous. Sequence similarity refers to how similar the actual nucleic acids are. Thus it is well known in the art that sequence similarity does not necessarily correspond to function.

The skilled artisan cannot envision the detailed structure of the isolated bacterium, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The bacterium itself is required. The growth characteristics and infection activity distinguishes the claimed bacterium strain only by what it does, i.e., by growth and infection, which are purely functional distinctions. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims describe an isolated bacterium by its function i.e., growth and infection abilities, however this description does not describe the claimed bacterium itself.

See also, *In The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), where the court held that a generic statement that defines a genus by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Applicants' arguments are not persuasive, since applicant has failed to point to or teach the identity of a bacterium that meets the claims limitations. Thus, in the absence of sequence information of the bacterium or some structural characteristics of the isolated bacterium, a bacterium described only by its ability to grow and infect fails to meet the written description requirements. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Claims 15-18 are drawn to an isolated *Leptospira* bacterium containing nucleic acids having nucleotide sequences that are at least about 80% identical to a nucleotide sequence selected from the group consisting of SEQ ID NO: 1-2, 4-7 and a complementary nucleotides sequence. Contrary to applicants' arguments the sequence of the isolated bacterium is unknown. Thus whether the sequence of the isolated bacterium is at least 80% identical to SEQ ID NO:1-2, 4-7 and a complementary nucleotides sequence is unknown. Applicants have not taught nucleotide sequences which are 80% identical to SEQ ID NO:1-2, 4-7 and the like. There are no representative examples of the claimed nucleotide.

Moreover, SEQ ID NO: 2, 4-7 are primers and thereby fail to teach sequences that comprise an isolated bacterium. Sequences having 80%, 85% or even 97% identity to either SEQ ID NO: 1-2, or 4-7 or complementary sequences fail to meet the written description provision of 35 UCS 112, first paragraph. Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, make clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the

invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). The specification only discloses SEQ ID NO: 1-2 and 4-7, there is no disclosure of nucleotide sequences with 80% identity to SEQ ID NO: 1-2 or 4-7 or complementary sequences comprised within the *Leptospira* bacterium. Thus, the structure of these nucleic acid molecules is not defined. Even though the claims recite sequence identification numbers, the skilled artisan cannot envision the detailed structure of the encompassed nucleic acid molecules since the specification has not defined what the 20% variables can be. Moreover, a skilled artisan cannot envision the detailed structure of complementary sequences. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method for determining sequence identity. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of expression. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. There is no evidence of an isolated bacterium that comprises at least 80% identity to SEQ ID NO: 1-2, 4-7 and a complementary nucleotides sequences.

The claims fail to recite the precise definition of the nucleic acid sequence with at least 80% identity to SEQ ID NO: 1-2, 4-7 and the complementary sequences. Currently the generic recitation of 80% identity is insufficient to support the claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal

Register at Volume 63, Number 114, pages 32639-32645. Therefore, the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

Applicants have presented a paper dated August 2002 that includes isolation of a pathogenic *L.fainei* bacterium that is equivalent to the strain deposited under WKID AGAL Accession NO. N95/69684. However, it is the examiner's position that applicants at the time of invention were not in possession of an isolated bacterium. Applicants failed to disclose a bacterium with the claimed characteristics. The fact that others did not find a bacterium that met the claim limitations until August 2002, well after applicants' filing date, only bolsters the examiner's position that applicants were not in possession of an isolated bacterium. Thus, applicants' arguments are not persuasive.

Therefore in view of the arguments, the rejection is maintained.

4. The new matter rejection of claims 1-20, 75 and 124-126 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

Neither the specification nor originally presented claims provides support for an isolated pathogenic *Leptospira* bacterium that a) belongs to serovar *hurstbridge* and is cross-reactive in a cross-agglutination assay with deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684; b) belong to sero group *Hurstbridge* and cross-

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agglutinates with share group antigens of deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684 and does not cross-agglutinate with members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and the bacterium comprises genomic DNA which is at least 40% homologous to the DNA derived from deposited *Leptospira fainei* strain WKID AGAL Accession NO. N95/69684 wherein the cross-reactive bacterium has the ability to grow under the recited conditions and can infect and/or cause the recited symptoms in a host.

Applicant did not point to support in the specification for an isolated pathogenic *Leptospira* bacterium that a) belongs to serovar hurstbridge and is cross-reactive in a cross-agglutination assay with deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684; b) belong to sero group Hurstbridge and cross-agglutinates with share group antigens of deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684 and does not cross-agglutinate with members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and the bacterium comprises genomic DNA which is at least 40% homologous to the DNA derived from deposited *Leptospira fainei* strain WKID AGAL Accession NO. N95/69684.

Applicant points to pages 4-6 which are drawn to definitions that define whether a bacterium would be considered a member of the serogroup Hurstbridge, or serological group of *Leptospira* whose members cross-agglutinate with shared group antigens of *L. fainei* deposited strain. However the specification fails to state the identity or structural characteristics of a cross-reactive strain that has the claimed growth characteristics or the claimed ability to infect. Examples 4 and 5 describe agglutination assays and

examples 8-11 teach how to determine whether a bacterium is related to the deposited strain. Applicants' have not pointed to a bacterium that meets the claimed characteristics. Definitions on how to categorize bacteria are not sufficient to provide support. Adequate support for the isolated bacterium is provided only for the structural identity of the bacterium, not characteristics that an unidentified bacterium will have.. However, none of the examples teach the identity of the isolated bacterium to which the claims are drawn.

There appears to be no teaching of an isolated pathogenic *Leptospira* bacteria with the claimed characteristics. There appears to be no support in the specification. Therefore, applicants must specifically point to page and line number support for an isolated pathogenic *Leptospira* bacterium as recited by the newly added amendments. Therefore, the new claims incorporate new matter and accordingly the rejection is maintained.

5. The rejection of claims 1-20, 75 and 124-126 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained for reasons already of record.

The claims are now drawn to an isolated pathogenic *Leptospira* bacterium that a) belongs to serovar *hurstbridge* and is cross-reactive in a cross-agglutination assay with deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684; b) belongs to sero

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group Hurstbridge and cross-agglutinates with share group antigens of deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684 and does not cross-agglutinate with members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and the bacterium comprises genomic DNA which is at least 40% homologous to the DNA derived from deposited *Leptospira fainei* strain WKID AGAL Accession NO. N95/69684.

Applicants have presented a paper dated August 2002 that includes isolation of a pathogenic *L.fainei* bacterium that is equivalent to the strain deposited under WKID AGAL Accession NO. N95/69684. However, it is the examiner's position that at the time of the invention, applicants had not made or used the isolated bacterium. Applicants are attempting to claim an isolated bacterium as of the filing date of the instant application, however applicants proof that such a bacterium exists was found several years after applicants' application. Moreover, the fact that the bacterium of the paper could not have been obtained without applicants' disclosure is not persuasive, since applicant is claiming that same bacterium as providing structural identity support for the claim. The instant claims are not drawn to method of classifying bacteria but to isolated bacterium. Therefore the fact the others used applicants method steps is not commensurate in scope to the instant claims and is therefore not found persuasive. However, applicants pointing to an isolated bacterium found several years after the submission of the instant application as its only form of proof of the structural identity of a bacterium is found to bolster the examiner's position that applicant was not enabled to make a claimed isolated bacterium at the time of applicants application.

The specification still however fails to teach the identity of strains with the claimed characteristics. The specification fails to teach examples of the isolated pathogenic *Leptospira* bacterium that is serologically cross reactive to the *Leptospira* strain WKID (AGAL Accession NO. N95/69684). Therefore, the specification fails to enable an isolated pathogenic *Leptospira* bacterium with the claimed characteristics.

Moreover, if the isolated pathogenic *Leptospira* bacterium that is serologically cross reactive to the *Leptospira* strain WKID (AGAL Accession NO. N95/69684) is not enabled, then similarly the bacterium containing the nucleotide sequences that are at least about 80% identical to SEQ ID NO:1-2, 4-7 and the complementary nucleotides sequences are not enabled. There is no teaching of bacterial primers which have an about 20% mismatch. The specification fails to identify an isolated bacterium with the recited characteristics. There is no teaching of how to determine which of the non-identical nucleotides will contain the 20% mismatch. Therefore, the specification fails to enable a bacterium containing the nucleotide sequences that are at least about 80% identical to SEQID NO: 1-2, 4-7 and the complementary nucleotide sequences. The specification is not enabled for any variants of a polynucleotide comprising a sequence having 80% identity to SEQ ID NO: 1-2, 4-7 or complementary sequences because the specification fails to teach that such sequences with 80% identity can be contained within the *Leptospira* bacterium that is cross reactive with the deposited strain.

The specification lacks any written description of a structure or relevant identifying characteristics of a representative number of polynucleotides encoding a representative number of polypeptides sufficient to allow one skilled in the art to

determine that the inventor had possession of the invention as claimed. The specification fails to teach what the critical nucleic acids are which can or cannot be modified and still achieve a nucleic acid with the required cross reactivity or what nucleic acids can be inserted, deleted or substituted within an 80% identical sequence.

In absence of further guidance from Applicants, the skilled artisan would have to discover what the appropriate additions, deletion and substitutions would be. Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of an isolated bacterium that a) belongs to serovar hurstbridge and is cross-reactive in a cross-agglutination assay with deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684; b) belong to sero group Hurstbridge and cross-agglutinates with shared group antigens of deposited *Leptospira* strain WKID AGAL Accession NO. N95/69684 and does not cross-agglutinate with members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and the bacterium comprises genomic DNA which is at least 40% homologous to the DNA derived from deposited *Leptospira fainei* strain WKID AGAL Accession NO. N95/69684, and further comprises sequences having 80% identity to SEQ ID NO:1-2, 4-7 and complementary sequences.

No working examples are shown containing the missing information. Without such information, one of skill in the art would have to de novo isolate the bacterium. Accordingly, one of skill in the art would be required to perform undue experimentation

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to produce such isolated bacterium. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

6. Claims 1-20, 75 and 124-126 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase "derived from" however it is unclear how to define "derived from". The specification does not teach how to make derivatives from *Leptospira fainei*. The derivative language is vague and indefinite because the characteristics needed to determine whether an unknown could be considered a derivative of *Leptospira fainei* are unknown. The specification neither discloses a definition for a derivative, nor does it teach a requisite amount of retained qualities needed or characteristics necessary to determine derivatives of *Leptospira fainei*. Therefore the claims are unclear.

The term "share group antigens" is a relative term which renders the claim indefinite. The term "share group antigens" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree "share group antigens." And one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus the metes and bounds of the terms cannot be determined.

Claim 19 refers to the term "characteristics of the microorganism deposited..." however it is a relative term which renders the claim indefinite. The characteristics are not defined by the claim, the specification does not provide a standard for ascertaining

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the requisite degree "characteristics", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, the claim is rejected.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines 
March 19, 2003

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